

Applicant: Sansoucy
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REMARKS

The Examiner has withdrawn all rejections under 35 U.S.C. §112, second paragraph. This determination is gratefully acknowledged.

Independent claim 27 stands rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,356,394 to Farley et al. (hereinafter "Farley"). The Examiner acknowledges that the valve shown in the Farley device is described as being openable by insertion of an instrument. However, the Examiner contends that Farley does not require insertion of an instrument in order to open the valve. The Examiner posits that infusion of a fluid of sufficiently high pressure would open the valve of Farley. Moreover, the Examiner states that the claim 27 limitation, wherein the occluding device is movable under fluid pressure, is a functional recitation of intended use. The Examiner concludes that since the Farley structure is capable of performing the intended use, it meets the limitation of the claims.

This determination is respectfully traversed.

The rejection of claim 27 is under 35 U.S.C. §102. It is well settled that to maintain an anticipation rejection, each element set forth in the claim, must be found within the four corners of the reference either expressly or inherently. The Examiner acknowledges that there is no

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express disclosure of using fluid pressure to open the Farley valve. In order to establish inherency, it is incumbent on the Examiner to show extrinsic evidence which must make it clear that the missing descriptive matter is necessarily present in the reference. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to meet inherency. *Scale Tech Inc. v. Retech/Tetra LLC*, 51 U.S.P.Q.2d 1055 (Fed. Cir. 1999); *In re Robinson*, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999).

Independent claim 27 recites an "occluding device which is removably supported within the transverse bore of the body". The recited occluding device is a structural limitation. Still further, the positioning of the occluding device against a resilient bias for movement by fluid pressure passed between the inlet and outlet conduits is a further structural limitation. This limitation is neither a functional recitation nor a recitation of intended use. Contrary to the Examiner's position, this limitation is a positive recitation of structure and function which must be considered by the Examiner in applying an anticipation rejection.

The Farley reference does not expressly disclose the structural and functional limitation of the occluding device being operable under fluid pressure. Furthermore, the assertion that the Farley device is capable of moving under fluid pressure is not inherent from the Farley

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disclosure. As noted above, to establish inherency, the Examiner must show extrinsic evidence which makes it clear that the missing limitation is necessarily present in the reference. The Examiner fails to point to any portion of the Farley disclosure which even suggests movement of the occluding device by anything other than the inserted instrument. Similarly, the Examiner cites no portion of the specification which leads one to believe that the occluding device of Farley could be opened by anything other than the instrument, let alone operation of fluid pressure. Lastly, the Examiner has provided no extrinsic evidence to supplement the inherency position.

Referring specifically to the Farley specification, the biasing means 44 (spring) is recited as clearly biasing the valve 24 in a sealed position where fluids are prevented from passing between the inlet and the outlet. (Column 3, lines 35-38). Thus, the only express description in Farley is that the biasing means biases the valve into a closed position such that it cannot be opened by fluid pressure therebetween. Again, at column 3, lines 53-55, the valve 24 is described as preventing fluids from traveling between the inlet and the outlet.

Referring next to column 4, line 3 et seq., the opening of the valve inlet is described. It is specifically stated that the instrument causes the ball to overcome the biasing means 44 thus placing the valve in an open position. There is no other discussion as to how to open the valve.

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In fact, the Farley specification states that the valve will remain open only as long as the instrument is inserted. Once the instrument has been removed, valve will return to a closed position. (Column 4, lines 23-28).

The Farley reference also describes a second preferred embodiment of the invention. Even with the second preferred embodiment, instrument insertion is required to overcome the spring biased valve. (Column 5, lines 13-18).

Thus, contrary to the Examiner's position, it appears clear that instrument insertion is actually required to open the valve of Farley. The passage of fluid therethrough is stated in Farley as being insufficient to overcome the spring bias on the valve. Moreover, given this recitation, there can be no clear intrinsic or extrinsic evidence which would lead one to believe that the Farley valve is moveable between an open and closed position by the mere passage of fluid therethrough. The Examiner's conclusion as to the capability of the Farley device with respect to valve opening is pure speculation and given the Farley disclosure, appears to be incorrect.

Accordingly, Farley fails to anticipate claim 27 of the present invention as it fails to clearly disclose all the elements of claim 27 either expressly or inherently. As such, claim 27


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and the claims which depend therefrom, are patentably distinct over the references of record.

Entry of this response in reconsideration is respectfully requested.

If there are any questions or if additional information is required, the Examiner is respectfully requested to contact applicant's attorney at the number listed below.

Respectfully submitted,



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